

Attorney Docket No.: DEX-0313
Inventors: Salceda et al.
Serial No.: 10/074,475
Filing Date: February 12, 2002
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REMARKS

Claims 1-17 are pending in the instant application. Claims 6 and 9-17 have been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants in this amendment. Claims 1-5, 7 and 8 have been rejected. Claims 1, 2, 3, 4, 5 and 8 have been amended. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement mailed July 16, 2003. Thus, in an earnest effort to advance the prosecution of this case, Applicants have canceled without prejudice non-elected claims 6 and 9-17. In light of the finality of this Restriction Requirement, Applicants reserve the right to file a divisional application to the canceled subject matter.

II. Amendment of Title

The Examiner suggests that the title is not descriptive of the elected claims directed to nucleic acids, vectors and host cells. Accordingly in an earnest effort to advance the prosecution of this case, Applicants have amended the title to "Breast Specific Nucleic Acids and Vectors and Host Cells Thereof".

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III. Objection to Specification

The specification has been objected to as containing embedded hyperlinks and/or other forms of browser executable code. Thus, in an earnest effort to advance the prosecution of this case, Applicants have amended the specification to inactivate all embedded hyperlinks by removing "http" and "www" and simply referring to the world wide web. No new matter is added by this amendment and entry is respectfully requested. Withdrawal of this objection is respectfully requested in light of these amendments.

IV. Objection to Claims

Claim 1 and claims 2-5, 7 and 8 by their dependency have been objected to as including non-elected subject matter. Thus, in accordance with the Examiner's suggestion, Applicants have amended the claims to be drawn to the elected subject matter, SEQ ID NO:156 encoding SEQ ID NO:285. Withdrawal of this objection is therefore respectfully requested.

V. Rejection of Claims 1-5, 7 and 8 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph - Lack of Enablement

Claims 1-5, 7 and 8 have been rejected under 35 U.S.C. § 101 as the Examiner suggests that the claimed invention lacks patentable utility due to its not being supported by a specific,

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substantial, and credible utility or, in the alternative, a well-established utility. These claims have also been rejected under 35 U.S.C. § 112, first paragraph for lack of enablement as the Examiner suggests that the asserted utility is speculative. Specifically, the Examiner suggests that application of the "Expressionist software program to propose allegations of sequences being associated with a particular type of cancer" provides "merely allegations without support based on scientific facts". In support of this statement, the Examiner suggests that it is unknown what criteria or parameters are relied upon by the Expressionist program to create these allegations and if these criteria or parameters are based on sound scientific reasoning.

Applicants respectfully traverse this rejection.

Contrary to the Examiner's suggestion, criteria and/or parameters relied upon by the Expressionist program to identify SEQ ID NO:156 as a breast specific nucleic acid are outlined in Example 2b at pages 113 through 115 of the instant specification. Further, the Examiner has provided no reasonable basis, as required by MPEP § 2164, to doubt that these parameters accurately identify breast specific nucleic acid molecules as stated in the instant specification. Thus, further proof from the inventors of an enabling use of the present invention is not required.

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However, further proof of the utility of BSNAs such as SEQ ID NO:156 of the present invention is provided in the specification in the gene expression analysis experiments described in Example 1 at pages 109-112 and the real-time quantitative PCR experiments described in Example 2 at pages 112-113 of the instant specification.

The case law on utility is quite clear; mere identification of a pharmacological activity of a claimed compound that is relevant to an asserted pharmacological use provides an immediate benefit to the public and thus satisfies the utility requirement. *Nelson v. Bowler*, 626 F.2d 853, 206 USPQ 881, 883 (CCPA 1980). Clearly identification of SEQ ID NO:156 as a breast specific nucleic acid molecule constitutes a pharmacological activity relevant to the asserted use as a diagnostic for breast cancer, thus satisfying the utility requirements of 35 U.S.C. § 101 and 35 U.S.C. § 112.

Withdrawal of these rejections is therefore respectfully requested.

VI. Rejection of Claims 1-5, 7 and 8 under 35 U.S.C. § 112, first paragraph - Written Description

Claims 1-5, 7 and 8 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor, at the time the invention was filed, had possession of the claimed invention. The Examiner has acknowledged the specification to meet the written description provisions of 35 U.S.C. § 112 with respect to SEQ ID NO: 156 and its full complement. However, the Examiner suggests that the written description provisions of 35 U.S.C. § 112, first paragraph are not met with respect to sequences that hybridize to SEQ ID NO:156 and sequences having a recited degree of sequence identity.

Applicants respectfully disagree as determination of hybridizing sequences and sequences having a recited degree of sequence identity with respect to SEQ ID NO:156 can be performed routinely by those of skill in the art and therefore need not be described in detail in the specification.

However, in an earnest effort to advance the prosecution of this case, Applicants have deleted these phrases from the claims.

Withdrawal of this rejection is therefore respectfully requested.

VII. Rejection of Claims 1-5, 7 and 8 under 35 U.S.C. § 112, second paragraph

Claims 1-5, 7 and 8 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly

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point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, with respect to claim 1, the Examiner suggests that the phrase "selectively hybridizes" is vague and indefinite. While Applicants respectfully disagree with the Examiner regarding clarity of this term, as discussed in Section VI, *supra*, this phrase has been deleted from the claim, thus mooting this rejection.

With respect to claims 2-5 and 8, the Examiner suggests that the phrase "according to" is vague and indefinite. Accordingly, this phrase has also been deleted from the claims.

Withdrawal of this rejection under 35 U.S.C. § 112, second paragraph, is therefore respectfully requested.

VIII. Rejection of Claims 1, 4 and 5 under 35 U.S.C. § 102(a)

Claims 1, 4 and 5 have been rejected under 35 U.S.C. § 102(a) as being anticipated by GenBank (Accession Number AF219946). The Examiner suggests that GenBank discloses a homo sapien mRNA sequence (Accession Number AF219946, residues 1358-5989) that has 100% similarity to SEQ ID NO:156 (residues 1-4632).

Applicants respectfully traverse this rejection.

The sequence disclosed in GenBank as Accession Number AF219946 contains 7,687 nucleotides. In contrast, SEQ ID NO:156 contains

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4632 nucleotides.

Accordingly, in an earnest effort to advance the prosecution of this case and to clearly distinguish the present invention from GenBank Accession Number AF219946, Applicants have amended claim 1, part (b) to state that the nucleic acid sequence consists essentially of SEQ ID NO:156. Since there is no teaching in GenBank Accession Number AF219946 relating to a sequence consisting essentially of SEQ ID NO:156 and its utility as a diagnostic cancer marker, this reference cannot anticipate the claims as amended.

Withdrawal of this rejection under 35 U.S.C. § 102(a) is therefore respectfully requested.

IX. Rejection of Claims 1-5, 7 and 8 under 35 U.S.C. § 102(e)(2)

Claims 1-5, 7 and 8 have been rejected under 35 U.S.C. § 102(e)(2) as being anticipated by Tang et al. (U.S. Patent 6,436,703). The Examiner suggests that the word "hybridizes" in claim 1 encompasses fragments and that Tang et al. discloses a human gene fragment (SEQ ID NO:9, residues 864-882) which matches 100% with a fragment of SEQ ID NO:156 (residues 3062-3080) of the instant invention. Further, the Examiner suggests that Tang et al. discloses nucleic acids which hybridize to SEQ ID NO:9, vector and obtaining polynucleotides from mammalian cells.

As discussed in Section VI, however, this phrase has been

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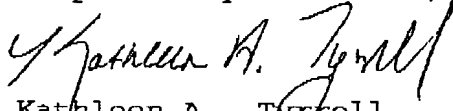
deleted from claim 1. Accordingly, this rejection over the teachings of Tang et al. relating to hybridizing sequences is now moot.

Withdrawal of this rejection is therefore respectfully requested.

X. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,


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